IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al. | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9202**

Bartle, J. February 4, 2014

Earle G. McNabb ("Mr. McNabb" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Ardelle McNabb, Mr. McNabb's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

use and the end of the Screening Period.[4] See Settlement Agreement § IV.B.1.a.

In September, 2011, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Winston Gandy, Jr., M.D. Based on an echocardiogram dated December 31, 2002, Dr. Gandy attested in Part II of claimant's Green Form that Mr. McNabb suffered from mild mitral regurgitation and chordae tendineae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation.[5] Dr. Gandy also attested that claimant had valvular repair or replacement surgery and required a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery.[6] Based

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4. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

5. Under the Settlement Agreement, the presence of chordae tendineae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c).

6. Dr. Gandy also attested that claimant suffered from mild aortic regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. These conditions are not at issue in this claim.

on such findings, claimant would be entitled to Matrix B-1, Level IV benefits in the amount of $194,550.[7]

In the report of claimant's echocardiogram, the reviewing cardiologist, Dev Narayan, M.D., stated that "Color flow and Doppler examinations suggest mild mitral regurgitation." Dr. Narayan, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitation jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

In December, 2011, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie determined there was no reasonable medical basis for Dr. Gandy's representation that Mr. McNabb had mild mitral regurgitation. Specifically, Dr. Gillespie explained, "Nyquist Limit was set at

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7. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she "had valvular repair or replacement surgery and requires a second surgery through the sternum within eighteen months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery." Settlement Agreement § IV.B.2.c.(4)(g). As the Trust does not contest that claimant has met these requirements, the only issue is whether he is eligible for benefits.

41 cm/sec which is too low. At this low limit, the jet was still only trace."[8]

Based on Dr. Gillespie's finding, the Trust issued a post-audit determination denying Mr. McNabb's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[9] In contest, Mr. McNabb submitted a letter and declaration of Ethan J. Podet, M.D., wherein he opined that claimant's echocardiogram demonstrated mild mitral regurgitation. Dr. Podet stated, in pertinent part, that:

> It is my understanding that "mild mitral regurgitation" is defined as a "regurgitant jet area / left atrial area ratio (of) more than 5% ...," as specified in the Green Form. I interpreted this as the comparison of the maximal jet area with the area of the left atrium in the same frame as the maximal jet area (after Helmcke, et al., Circulation 1987 and Singh, et al., Am. J. Cardiol. 1999). By this criterion, Mr. McNabb's mitral regurgitation is mild. Please see my tracings of the jet and atrium (enclosed).
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> The auditor indicates that the regurgitation was less than 'mild' because

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8. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA."

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. McNabb's claim.

> the Nyquist Limit of 41 cm/sec was "too low. At this low limit, the jet was still only trace." I do not think that the Nyquist setting of 41 cm/sec or the grading of 'mild' mitral regurgitation was "beyond the bounds of medical reason." Though the Nyquist limit is lower than the 50 - 60 cm/sec setting described as "standard technique" in the American Society of Echocardiography Recommendations for Evaluations of the Severity of Native Valvular Regurgitation (Zoghbi, et al., 2003), I do not think this invalidates the assessment of 'mild.'
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> This is because such a Nyquist limit setting should not affect the presence or absence of the jet, though it may affect its size and color. Had a Nyquist limit of 50 - 60 cm/sec been used, a jet/[left atrial] area ratio of greater than 10% might still have been measured. The abnormal structure of the valve evident in the 2002 [echocardiogram] (around frames 00361:11 and 00374:12) and the ensuing mitral valve replacement 4 years later argue in favor of the reasonableness of the assessment of 'mild' mitral regurgitation.

In addition, claimant argued that the range for a Nyquist limit of between 50-60 cm/sec was established in 2003, after claimant's echocardiogram was conducted.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Gillespie submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. McNabb had mild mitral regurgitation. Dr. Gillespie stated, in relevant part, that:

> 10. With respect to mitral regurgitation, I confirm my finding at audit that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had mild mitral regurgitation.

At the time of audit, I noted a low Nyquist limit of 41 cm/sec. In his letter submitted at Contest, Dr. Podet asserts that a Nyquist Limit under 50 cm/sec is insufficient to support the conclusion that Claimant's mitral regurgitation was trace, noting that this standard was not historically used to assess degree of [mitral regurgitation]. While a lowered Nyquist Limit over accentuates mitral regurgitation, this was not the only parameter I considered in determining that there is no reasonable medical basis for the Green Form representation of mild mitral regurgitation. For example, Claimant's mitral regurgitant 'jet' lasts less than 4 frames on this study, which is consistent with mitral valve backflow and not true mitral regurgitation. I reviewed the 3 frames traced by Dr. Podet, each of which demonstrates at most trace mitral regurgitation. The jets lasted less than 4 frames and the low Nyquist Limit accentuated even that small jet. Additionally, the left atrium was foreshortened on the views he measured which would artificially increase the RJA/LAA ratio by decreasing the left atrial size.

11. Dr. Podet also states that Claimant's "ensuing mitral valve replacement 4 years later argues in favor of the reasonableness of the assessment of mild mitral regurgitation." This statement does not take into account that the claimant had a normal left ventricular ejection fraction (LVEF) at the time of the echocardiogram done on 12/31/2002. By the time of mitral valve replacement, his LVEF was severely reduced and the left ventricle was dilated. The most plausible explanation for the degree of mitral regurgitation would be a mitral valve annulus dilated secondary to the dilated ventricle, which is a known and common finding in the setting of a dilated cardiomyopathy. There was a clear change in left ventricular

> function between the time of the study done on 12/31/2002 and the subsequent surgery in November 2006. As is often the case, the cause of the dilated cardiomyopathy is unclear.
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> 12. Dr. Podet also asserts that the mitral valve was structurally abnormal and thus mild mitral regurgitation could have been present. I agree the valve was structurally abnormal with significant calcification particularly in the annulus. However, there was no significant mitral regurgitation, and the presence of calcification does not imply that mitral regurgitation is present. For all of these reasons, I find that there is no reasonable medical basis for the Attesting Physician's finding that Claimant had mild mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Mr. McNabb's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why his claim should be paid. On July 11, 2012, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8911 (July 11, 2012).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 15, 2012, and claimant submitted a sur-reply on December 3, 2012. Under the

Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for finding that Mr. McNabb suffered from at least mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. McNabb reasserts the arguments made in contest, namely, that Dr. Podet's letter and declaration provide a reasonable medical basis for Dr. Gandy's representation of mild mitral regurgitation. He also argues that the auditing cardiologist did not identify a measurement of regurgitation less than 5%, did not address his application of the Singh criteria to his audit, and did not rebut Dr. Podet's letter or declaration. In addition, Mr. McNabb contends that the Trust's reliance on PTO No. 2640 is misplaced because the circumstances at issue there are not present here. Moreover, claimant argues that the auditing cardiologist's opinion should be disregarded because Dr. Gillespie did not consider claimant's worsening condition, including a heart catheterization dated August 19, 2004 and echocardiograms dated November 6, 2006 and November 7, 2006 echocardiogram, each of which claimant contends support "progression of [claimant's] valvular heart disease." Finally, claimant notes that his echocardiogram was performed in the Screening Program and contends that there can be a reasonable medical basis for a particular finding even when two cardiologists disagree.

In response, the Trust argues that claimant did not establish a reasonable medical basis for Dr. Gandy's representation of mild mitral regurgitation. Specifically, the Trust contends that neither Dr. Podet's submissions nor the

arguments advanced by claimant rebut Dr. Gillespie's audit finding of trace mitral regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that Mr. McNabb had mild mitral regurgitation prior to the end of the Screening Period. Specifically, Dr. Vigilante explained, in pertinent part:

> I reviewed the tape of the Claimant's echocardiogram of attestation. It was stated that the Claimant's name was "Earl McNabb." The date of December 31, 2002 was documented.... All of the usual echocardiographic views were obtained. However, this was an incomplete study since there was no color Doppler evaluation for mitral regurgitation in the apical two chamber view. Mitral regurgitation was only evaluated in the apical four chamber view. In addition, this was a poor quality study with increased echo gain and increased color gain. There was color persistence. In addition, there was an inappropriately low Nyquist limit of 41 cm/sec at a depth of 24 cm in the parasternal long-axis and apical four chamber views. In spite of these limitations, the study was interpretable.
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> .... Mitral regurgitation was not identified in color Doppler evaluation in the parasternal long-axis view. Visually, in the apical four chamber view, there was no sustained jet of mitral regurgitation. I digitized the cardiac cycles in the apical views in which color flow mapping occurred. On multiple stop frames, I was unable to identify a sustained jet of mitral regurgitation. There was a slight bit of backflow noted at the beginning of systole. There was no mitral regurgitation seen by mid systole. I was able to planimeter the left atrium in the mid portion of systole in the apical four chamber view. The LAA was 20.3 cm2. There was no evidence of mild mitral regurgitation on this study since

> there was no evidence of a sustained mitral regurgitant jet in the apical four chamber view. There was no color flow mapping in the apical two chamber view. I reviewed Dr. Podet's diagrams. I also reviewed the time frames that he documented in these diagrams. In each of these time frames, the supposed RJA in still frame was only backflow. Dr. Podet's measurement of the LAA's [sic] was inaccurate in his diagrams. He had off-axis views. The correct LAA in the apical four chamber view was 20.3 cm2.

In response to the Technical Advisor Report, Mr. McNabb argues that the Technical Advisor did not apply the proper criteria to his claim because Dr. Vigilante looked for a "sustained mitral regurgitation jet" while, according to claimant, the Feigenbaum and Weyman texts "do not mention the duration of the jet." In addition, claimant contends Dr. Podet accurately measured the LAAs because he measured them in the same frames as the regurgitant jet consistent with Singh.[11]

After reviewing the entire Show Cause Record, we find the claimant's arguments are without merit. Contrary to claimant's assertion, the opinion of his expert, Dr. Podet, does not provide a reasonable medical basis for Dr. Gandy's representation that claimant had mild mitral regurgitation.[12] We

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11. Claimant references our decisions in two other show cause claims as supportive of Dr. Podet's methodology. Dr. Podet's opinions in other claims, however, are irrelevant to the disposition of Mr. McNabb's claim.

12. We also reject claimant's argument that he may establish a reasonable medical basis for Dr. Gandy's representation of mild mitral regurgitation based on the December 31, 2002 echocardiogram by reference to other echocardiograms performed as many as four years later.

are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Gillespie reviewed claimant's echocardiogram and determined that, notwithstanding the low Nyquist setting, "the jet was still only trace." Dr. Podet identified a number of times and measurements on the tape he contended demonstrated mild mitral regurgitation. Dr. Gillespie reviewed these time frames and observed that the regurgitant jets lasted less than four frames consistent with mitral valve backflow and not true mitral regurgitation. Dr. Vigilante also reviewed claimant's echocardiogram and determined that it did not demonstrate mild

mitral regurgitation. Dr. Vigilante "was unable to identify a sustained jet of mitral regurgitation." Dr. Vigilante further reviewed the specific frames referenced by Dr. Podet and determined, "In each of these time frames, the supposed RJA in still frame was only backflow." Such unacceptable practices by claimant's cardiologists cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from mild mitral regurgitation.

We also reject claimant's argument that Dr. Vigilante did not apply the appropriate standard in evaluating Mr. McNabb's echocardiogram. Specifically, Dr. Vigilante concluded that "there was no evidence of a sustained mitral regurgitant jet." Although claimant objects to Dr. Vigilante's use of "sustained" jets to evaluate the level of mitral regurgitation, we have repeatedly held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of regurgitation are representative of the level of regurgitation throughout an echocardiogram." Mem. in Supp. of PTO No. 8659, at 10 (Aug. 8, 2011) (quoting Mem. in Supp. of PTO No. 6997, at 11 (Feb. 26, 2007)); see also In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). To conclude otherwise would allow claimants who do not have the requisite level of regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

In addition, to the extent claimant attempts to rely on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that he had mild aortic regurgitation, such reliance is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist and the Technical Advisor determined that claimant's echocardiogram demonstrated, at most, trace mitral regurgitation. Adopting claimant's argument would allow a claimant to recover benefits without meeting the requirements of the Settlement Agreement.[13]

Finally, we reject claimant's assertion that he is entitled to Matrix Benefits because his eligibility echocardiogram was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b)

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13. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement, "An echocardiographer could not reasonably conclude that mild mitral regurgitation was present on this study even taking into account inter-reader variability."

> who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See Mem. in Supp. of PTO No. 2662, at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had at least mild mitral

regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Mr. McNabb's claim for Matrix B, Level IV benefits and the related derivative claim submitted by his spouse.